

**CAREALL PAIN RELIEF PM EXTRA STRENGTH- acetaminophen,
diphenhydramine hcl tablet
New World Imports, Inc**

Drug Facts

Active Ingredients

Acetaminophen 500mg

Diphenhydramine HCl 25mg

Purpose

Pain reliever

Nighttime sleep aid

Keep Out of reach of Children

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) right away. Quick Medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Uses

Temporarily relieves occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take

- More than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away.

Do not use:

- in children under 12 years of age
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- if you have even had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- do not drive a motor vehicle or operate machinery
- avoid alcoholic drinks

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness
- pain gets worse or last for more than 10 days.
- fever gets worse or last for more than 3 days
- redness or swelling are present
- new symptoms occur. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Directions

Do not use more than directed. (see overdose warning)

Adults and children 12 years of age and older: Take 2 caplets at bedtime. Do not take more than 2 caplets in 24 hours

Children under 12 years: do not use

Inactive Ingredients

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD and C blue 1, hypromellose, lactose, magnesium, stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

NDC 51824-108-50



Extra Strength For Adults

Pain Relief PM

ACETAMINOPHEN 500 mg

Diphenhydramine HCl 25 mg

▶ Pain Reliever

▶ Nighttime Sleep-Aid

†Compare to the active ingredients of Tylenol®PM Extra Strength Caplets



50 CAPLETS

DO NOT USE IF UNPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each caplet) Purpose
Acetaminophen 500 mg.....Pain reliever
Diphenhydramine HCl 25 mg.....Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
 ■ more than 4,000 mg of acetaminophen in 24 hours
 ■ with other drugs containing acetaminophen
 ■ 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
 ■ skin reddening ■ blisters ■ rash
 If a skin reaction occurs, stop use and seek medical help right away.

Do not use
 ■ in children under 12 years of age
 ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
 ■ with any other product containing diphenhydramine, even one used on skin
 ■ if you have ever had an allergic reaction to this product or any of its ingredients

Distributed by: CareALL Products
160 Athens Way
Nashville, TN 37228
www.careallproducts.com



This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Tylenol®PM.

COATING FREE AREA FOR LOT/EXP

Drug Facts (continued)

Ask a doctor before use if you have
 ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are
 ■ taking the blood thinning drug warfarin
 ■ taking sedatives or tranquilizers

When using this product
 ■ drowsiness will occur ■ avoid alcoholic drinks
 ■ do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if
 ■ sleepiness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
 ■ pain gets worse or lasts more than 10 days
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ new symptoms occur

These could be signs of a serious condition.
If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** **Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
 ■ do not take more than directed (see overdose warning)
 ■ adults and children 12 years and over: take 2 caplets at bedtime; do not take more than 2 caplets of this product in 24 hours
 ■ children under 12 years: do not use

Other information
 ■ store between 20-25°C (68-77°F) in a dry place

Inactive ingredients
 colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?
 Call 1-944-705-4394 Mon - Fri 8:30 AM - 5 PM EST

STOP PEELING

CAREALL PAIN RELIEF PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-108
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
POVIDONE (UNII: FZ989GH94E)
STARCH, CORN (UNII: O8232NY3SJ)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
COPOVIDONE K25-31 (UNII: D9C330MD8B)
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;1031
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-108-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/23/2024	

Labeler - New World Imports, Inc (075372276)

Revised: 8/2024

New World Imports, Inc